MAY - 5 2011

510(k) Summary

Name of Firm
Custom Spine, Incorporated
1140 Parsippany Blvd, Suite 201
Parsippany, NJ 07054
Phone Number: (973) 808-0019
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Official Correspondent
Saad Attiyah
Manager of Regulatory Affairs and Quality Assurance
1140 Parsippany Blvd, Suite 201
Parsippany, NJ 07054
Phone Number: (973) 265-5036
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Establishment Number
3005129649

Device Name
Legally Market Trade Name: ISSYS LP Spinal Fixation System
Common Name: Pedicle Screw System
Device Classification: Class III
Regulation Number: 21 CFR 888.3070
Device Product Codes: NKB, KWP, MNI, MNH, KWQ

Predicate Devices
ISSYS LP Spinal Fixation System (K070281, K072866)
Moss Miami Spinal System (K933881, K955348, K964024, K983583, K022623)
Optima Spinal System (K031585)

Description of Modified Device
The subject ISSYS LP Spinal Fixation System includes will include auxiliary connectors in the form of side to side, axial connectors, and offset connectors with various length arms up to 35mm. Additionally, pre bent 6.0 mm diameter rods, in various lengths, will be provided to be used with the side to side connectors, if required. These connectors are intended to be used with 5.5 mm, 6.0 mm, and 6.35 mm diameter rods. These additional components are to be used in the posterior non-cervical spine (T1-S1). The indications for use are not affected by the addition of these components.

Indications for Use

The ISSYS LP Spinal Fixation System is intended to help provide immobilization and stabilization of the spinal segments as an adjunct to fusion of the lumbar and/or sacral spine, specifically as follows:

For pedicular use: When used as pedicle screw fixation system of the non cervical posterior spine in skeletally mature patients, these systems are indicated for one or more of the following: degenerative spondylolisthesis with objective evidence of neurological impairment, fracture, dislocation, scoliosis, kyphosis, spinal tumor, and failed previous fusion (pseudoarthrosis).

In addition, this system is indicated for pedicle screw fixation in skeletally mature patients with severe spondylolisthesis (grade 3 & 4) at the L5-S1 joint having fusion with autogenous bone graft, having the device fixed or attached to the lumbar and sacral spine (with pedicle placement at L3 and below) with removal of the implants after the development of a solid fusion mass.

The ISSYS LP Spinal Fixation System is also intended to provide immobilization and stabilization of the spinal segments in the thoracic, lumbar, and sacral spine as an adjunct to fusion of degenerative disc disease and spondylolisthesis other than severe spondylolisthesis (grade 3 and 4) at L5-S1 or degenerative spondylolisthesis with objective evidence of neurological impairment.

When used as non pedicular fixation system:

The ISSYS LP Spinal Fixation System, when used as an anterior screw fixation system and posterior sacral/iliac screw fixation system are indicated for the following:

- Degenerative disc disease of the thoracic and lumbar spine (defined as back pain of discogenic origin with degeneration of the disc confirmed by history and radiographic studies).
- Spondylolisthesis
- Fracture
- Spinal deformities such as scoliosis, kyphosis, lordosis
- Tumor
- Revision of failed fusion attempts
- Pseudoarthrosis
- Spinal Stenosis

When used in the anterior indication the ISSYS LP Spinal Fixation System is indicated for use in the thoracic and lumbar spine.

Materials

These materials are manufactured from ASTM F-136 implant grade titanium alloys.

Performance Data

Performance data per ASTM F1717 and F1798 were submitted to characterize the subject ISSYS LP Spinal Fixation system components in this notification.

Performance Data

Documentation is provided that the new component of the Custom Spine ISSSYS LP Spinal Fixation System is substantially equivalent to the predicate devices in terms of materials,

mechanical properties, and indications for use. An engineering analysis and testing demonstrate compliance with FDA's *"Guidance for Spinal Systems 510(k)'s"* Dated May 3, 2004 was completed for the ISSYS LP Spinal Fixation System, including the subject components.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Room –WO66-G609
Silver Spring, MD 20993-0002

MAY - 5 2011

Custom Spine, Inc.
% Mr. Saad Attiyah
Manager of Regulatory Affairs/Quality Assurance
1140 Parsippany Boulevard, Suite 201
Parsippany, New Jersey 07054

Re: K111099
Trade/Device Name: ISSYS LP Spinal Fixation System
Regulation Number: 21 CFR 888.3070
Regulation Name: Pedicle screw spinal system
Regulatory Class: III
Product Code: NKB, MNI, MNH, KWQ, KWP
Dated: February 14, 2011
Received: April 20, 2011

Dear Mr. Attiyah:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical

device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please go to http://www.fda.gov/AboutFDA/CentersOffices/CDRH/CDRHOffices/ucm115809.htm for the Center for Devices and Radiological Health's (CDRH's) Office of Compliance. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

for

Mark N. Melkerson
Director
Division of Surgical, Orthopedic
and Restorative Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Indications for Use

510(k) Number (if known): K111099
Device Name: ISSYS LP Spinal Fixation System

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- Spinal Stenosis

When used in the anterior indication the ISSYS LP Spinal Fixation System is indicated for use in the thoracic and lumbar spine.

Prescription Use __X__ AND/OR Over-The-Counter Use _____
(Part 21 CFR 801 Subpart D) (21 CFR 807 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

(Division Sign-Off)
Division of Surgical, Orthopedic,
and Restorative Devices

510(k) Number K111099